REMARKS

Claims 1-20 and 22-29 are pending in the present application.

At the outset, Applicants wish to thank Examiner Soroush and Examiner Padmanabhan for the helpful and courteous discussion with their undersigned Representative on November 8, 2006. During this discussion, several amendments and arguments were discussed to address the outstanding rejections. The content of this discussion is believed to be reflected in the amendments and remarks herein. Reconsideration of the outstanding rejections is requested.

The rejections of Claims 14-21 under 35 U.S.C. §112, first paragraph (enablement), are obviated in part by amendment and traversed in part.

With respect to methods of treatment claims, Claims 14-20, these have been amended based on the Examples of the present application, many of which are drawn to methods for treating an arthritic condition (see, *inter alia*, Examples 1-2). Applicants submit that the scope of the presently claimed invention is fully enabled by the present specification.

MPEP § 2164.01 states:

> The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.

Applicants submit that with the present application in hand, and with particular reference to the Examples 1-2 at pages 23-26, the skilled artisan would be able to readily practice the full scope of the claimed invention without undue experimentation. Moreover, Applicants submit that the Examples of the present specification clearly establish the efficacy of the claimed compositions for treatment of arthritic conditions. Therefore, the enablement

rejection over the method of treatment claims should be withdrawn.

In regard to the methods of prevention claims, new Claims 22-29, the Examiner alleges that "preventing" inflammatory disease is not enabled by the present specification. Applicants disagree. The Examiner is referred to Examples 3 and 4 of the present specification in which ornithine or the mixture of branched amino acids (BCAA) were administered to model mice (with spontaneously-developed chronic rheumatism) *before* the development of the disease. The results in these Examples clearly indicate that the disease development was depressed in the ornithine (or BCAA)-administered group. Applicants submit that these examples clearly and exactly show the effect of the present invention for preventing an inflammatory disease. Thus, Applicants submit that the skilled artisan would be readily able to administer to a subject in need thereof an effective amount of ornithine and/or one or more branched amino acids with the effect of preventing an inflammatory disease.

In view of the foregoing, Applicants request withdrawal of this ground of rejection.

The rejections of (a) Claims 14-16, 20, and 21 under 35 U.S.C. §102(b) over Moretti, (b) Claims 14-17, and 20 under 35 U.S.C. §102(b) over Meisner; (c) Claim 14 under 35 U.S.C. §102(b) over Akimoto; and (d) Claims 18 and 19 under 35 U.S.C. §103(a) over Moretti in view of Fisher et al and Ansel et al, are respectfully traversed.

At the outset, Applicants submit that the cited prior art (Moretti, Meisner, and Akimoto) each suffer the same basic defect in that these references only generically disclose the possibility of using either ornithine, valine, or leucine, respectively, in the prophylaxis or treatment of many disorders, including inflammatory disorders. However, prophylaxis or treatment of inflammatory disorders is just one of many cited disorders (see, for example,

page 3, lines 14-22 of Moretti). Applicants submit that these references fail to disclose or suggest the claimed invention with sufficient specificity such that the skilled artisan would envision the same. This is particularly the case for the treatment of arthritis as Meisner and Akimoto are unrelated to arthritis, instead dealing with wound healing (Meiner) and (Akimoto). Moreover, Moretti, Meisner, and Akimoto fail to enable the methods as presently claimed, which is absolutely required to support an anticipation rejection.

Even further, it should be noted that claims of the present application require the co-administration of ornithine and at least one branched amino acid. Moretti, Meisner, and Akimoto each only disclose the administration of ornithine, valine, or leucine, respectively. Applicants remind the Examiner that the standard for determining anticipation requires that the reference "must teach every element of the claim" (MPEP §2131). In view of the differences in the active ingredients administered, Applicants submit that Moretti, Meisner, and Akimoto cannot anticipate the claimed invention. Therefore, this ground of rejection should be withdrawn.

At best, the disclosures of Moretti, Meisner, and Akimoto, individually or together, provide a motivation to experiment or could be viewed as making it "obvious to try" to arrive at the present invention. However, "obvious to try" has long been held *not* to constitute obviousness. *In re O'Farrell*, 7 USPQ2d 1673, 1680-81 (Fed. Cir. 1988). A general incentive (i.e., "a desire to enhance the production of 2'-deoxyribonucleosides") does not make obvious a particular result, nor does the existence of techniques by which those efforts can be carried out. *In re Deuel*, 34 USPQ2d 1210, 1216 (Fed. Cir. 1995).

The proper standard for determining obviousness is whether the art itself discloses or suggests all the limitations of the claimed invention. Indeed, MPEP §2142 states: "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must

be some suggestion or motivation... to modify the reference... Second, there must be a reasonable expectation of success. Finally, the prior art reference... must teach or suggest all the claim limitations." Applicants submit that the disclosures of Moretti, Meisner, and Akimoto fail to meet this threshold test as there is simply no suggestion in these references to combine their disclosures or to arrive at the claimed invention.

Further, Applicants direct the Examiner's attention to the present specification which clearly establishes the benefits flowing from the claimed invention none of which are apparent from the disclosures of Moretti, Meisner, and Akimoto. In this regard, Applicants specifically wish to note that Moretti merely disclose that carnitine reduces the ceramide levels in a cell, without providing any data of the therapeutic effect. They also fail to give a sufficient explanation of the relationship between ceramide in a cell and rheumatism. There is also no data demonstrating that a basic amino acid, other than carnitine (i.e., ornithine) has an effect of the same kind. With respect to the beneficial effects flowing from the co-administration of ornitine and at least one branched amino acid, the Examiner is referred to Table 6 of Example 9 (below).

Table 6: Effect of Combined Ornithine and BCAA on CIA

Drug	Ratio of Individuals with Arthritis (%)	Arthritis Score
Control Group	100	3.2
Ornithine	30	0.8
BCAA	30	1.2
Combined Group	0	0

These results unequivocally show that the combined administration of ornithine and

branched amino acids absolutely inhibited disease development, which could not be achieved with the individual administration of the active ingredients. Applicant submit that these results would not flow from the limited disclosure of Moretti, as well as Meisner and Akimoto.

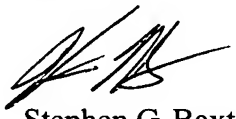
Fisher et al and Ansel et al are merely cited as disclosing food and drinks to which the active ingredients may be added. However, these references fail to compensate for the aforementioned deficiencies in the disclosures of Moretti, Meisner, and Akimoto. As such, even when viewing the combined with the disclosures of Moretti, Fisher et al and Ansel et al, the present invention would not be obvious.

Accordingly, Applicants request withdrawal of these grounds of rejection.

Applicants submit that the present application is in condition for allowance. Early notification to this effect is respectfully requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Stephen G. Baxter, Ph.D.
Registration No. 32,884

Vincent K. Shier, Ph.D.
Registration No. 50,552

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413-2220
(OSMMN 08/03)